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(54) Title of the Invention: Home Treatment Assisting System

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Specifications

1. Title of the Invention

Home Treatment Assisting System

2. What Is Claimed Is

(1) A home treatment assisting system, characterized by comprising:
a living body information measuring device that measures living body information of the patient;
a terminal device installed on the side of the patient;
a central management device installed at the medical institution that treats the patient; and
a communication means that links the terminal device and central management device;
wherein the terminal device is equipped with a computer, a data input means and a display device, in order to display the information received from the central management device, accept the information input by the patient through the data input means and send the input information to the central management device; and
wherein the central management device is equipped with a computer, a data input means, a display device and a memory for storing the patient's medical data and treatment indicators including treatment limitations in order to generate the required questions based on the patient information received from the terminal device and send the questions to the terminal device while at the same time receive the replies to the questions, and also to execute a first program that performs diagnosis, determines the treatment method and makes judgment on the need for direct examination at the medial institution based on the information received from the terminal device as well as the patient's medical data and treatment indicators stored in the memory and stores the results in the memory and also sends them to the terminal device.

(2) A home treatment assisting system according to Claim (1), characterized in that the central

management device is capable of executing a second program that displays the medical data and treatment indicators on the display device, while changing the treatment indicators using the data input means, according to the request of the attending doctor.

(3) A home treatment assisting system according to Claim (1), characterized in that the central management device contains multiple procedures to generate patient condition indicators and perform diagnosis, determine the treatment method and make judgment on the need for direct examination at the medial institution based on the information received from the terminal device as well as the medical data stored in the memory, where the procedure to be applied is selected based on the condition indicators.

3. Detailed Explanation of the Invention

[Industrial Field of Application]

The present invention relates to a system that assists the home treatment of various types of diseases that require treatment over an extended period of time.

[Prior Art]

Currently, many patients suffering from chronic diseases requiring treatment over an extended period of time, such as diabetes and hypertension, are mainly managed through outpatient visit. However, these diseases, due to the fact that they require treatment over an extended period of time, are associated with an increased burden on the part of the patient in terms of having to visit the hospital, etc., when the number (or frequency) of outpatient visits increases. When the number of outpatient visits decreases, on the other hand, detailed management cannot be ensured and the quality of treatment drops.

Accordingly, systems that manage diabetes, etc., at home by means of computer communication have been proposed.

These computer systems are disclosed in many publications of patent applications, such as the following:

Japanese Patent Application Publication No. Sho 60-261426
Japanese Patent Application Publication No. Sho 61-234846
Japanese Patent Application Publication No. Sho 62-041638
Japanese Patent Application Publication No. Sho 62-197032
Japanese Patent Application Publication No. Sho 62-275433
Japanese Patent Application Publication No. Sho 63-051838
Japanese Patent Application Publication No. Sho 63-075878
Japanese Patent Application Publication No. Sho 63-262123
Japanese Patent Application Publication No. Sho 64-025837
Japanese Patent Application Publication No. Sho 64-082176
Japanese Patent Application Publication No. Hei 1-091834
Japanese Patent Application Publication No. Hei 1-206756

[Problems to Be Solved by the Invention]

However, these conventional systems present problems in that they only report changes in the clinical condition of the patient or are able to only provide instructions on simple treatment methods.

Also, even those communication systems that can provide instructions on treatment methods do so using a predefined program and therefore it has been difficult, using conventional systems, to provide accurate, safe instructions for patients who are exhibiting a complex clinical condition. Furthermore, conventional systems do not provide a function whereby the program itself determines instruction limits without the doctor's examination or judgment, and thus the doctor must directly manage patients whose treatment method is difficult to determine.

[Object of the Invention]

The object of the present invention is to address the aforementioned problems associated with conventional systems. To be specific, it is the object of the present invention to provide a home treatment system that enables safe, accurate treatment of various types of diseases at home, while reducing the number of outpatient visits and lessening the burden on the patient as well as the doctor.

Particularly when a treatment method is instructed using a computer, setting limitations on the treatment method in case of anticipated changes in the patient's clinical condition is essential in preventing erroneous treatment. With conventional systems that do not

consider these limitations on treatment method, however, a treatment that is dangerous for the patient exhibiting a given change in clinical condition is sometimes instructed. With the present invention, on the other hand, the scope of computer instructions is limited so as to allow for instruction of a safe, accurate home treatment.

[Means for Solving the Problems]

To achieve the aforementioned object, the present invention comprises: a living body information measuring device that measures living body information of the patient; a terminal device installed on the side of the patient; a central management device installed at the medical institution that treats the patient; and a communication means that links the terminal device and central management device; wherein the terminal device is equipped with a computer, a data input means and a display device in order to display the information received from the central management device, accept the information input by the patient through the data input means and send the input information to the central management device; wherein the central management device is equipped with a computer, a data input means, a display device and a memory for storing the patient's medical data and treatment indicators including treatment limitations, in order to generate the required questions based on the patient information received from the terminal device and send the questions to the terminal device while at the same time receive the replies to the questions, and also to execute a first program that performs diagnosis, determines the treatment method and makes judgment on the need for direct examination at the medial institution based on the information received from the terminal device as well as the patient's medical data and treatment indicators stored in the memory and stores the results in the memory and also sends them to the terminal device.

The present invention is also characterized in that the central management device is capable of executing a second program that displays the medical data and treatment indicators on the display device, while changing the treatment indicators using the data input means, according to the request of the attending doctor.

Furthermore, the present invention is characterized in that the central management device contains multiple procedures to generate patient condition indicators and perform diagnosis, determine the treatment method and make judgment on the need for direct examination at the medial institution based on the information received from the terminal device as well as the medical data stored in the memory, where the procedure to be applied is selected based on the condition indicators.

[Operation]

Accordingly, the present invention allows the patient, after having received treatment instructions based on a diagnosis by the attending doctor, to receive the necessary changes to the treatment by means of communication with the computer memory in which the treatment instructions are stored.

Based on such computer communication, the patient can directly access the computer memory storing his or her living body information that can be measured at home, in order to record a progress of treatment in a chronological manner while at the same time receive optimal treatment instructions based on the recorded progress of treatment.

According to the present invention, the scope of treatment method is limited by the attending doctor beforehand, and therefore the patient can receive treatment based on the progress of treatment and also within the aforementioned limitations, which eliminates without fail such drawbacks as an erroneous treatment being performed based on a diagnostic error of the computer.

Furthermore, the system proposed by the present invention allows the attending doctor to know the progress of the patient's treatment at any time, and change the treatment method or limitations associated with treatment indicators in a desired manner based on the progress of treatment.

Furthermore, the present invention reliably instructs the patient of a need for major change to the treatment method or for direct diagnosis by the attending doctor, thereby allowing a safe, optimal treatment to be continued.

[Examples]

An example where a home treatment assisting system conforming to the present invention is used for the management of diabetes is explained below using drawings.

[1] System Structure

Fig. 1 shows the basic structure of the system used in this example, which comprises a blood sugar

measuring device 10 for measuring the glucose level in the patient's blood, a terminal device 20 installed at the patient's home, work place or other location where the patient conducts his or her daily activity, a central management device 30 installed at the medical institution where the attending doctor works, and a communication means 40 that allows for information exchange between the terminal device 20 and central management device 30. For your information, although Fig. 1 shows only one terminal device, the actual system has multiple terminal devices that are structured in the exact same manner. Accordingly, only one terminal device is mentioned in the following explanation.

The blood sugar measuring device 10 draws a trace amount of blood from the patient using a spring lancet, measures the glucose level in the drawn blood, and outputs the result as electrical signals to a data input means 22 of the terminal device 20.

The terminal device 20 comprises a computer 21, a keyboard 221 and a data input interface 222 that together serve as the data input means 22, and a liquid crystal display device 23. The computer 21 can display on the display device 23 the information received from the central management device 30 via the communication means 40, such as questions regarding the symptoms and implementation condition of the treatment method, instructions on blood sugar test, etc., as well as the diagnosis result, instructions on the treatment method and other information, while also allowing the patient to input replies to the aforementioned questions or measurement results via the keyboard 221 and enabling online input of the output signals from the blood sugar measuring device 10 via the data input interface 222, wherein this computer is programmed in such a way that these input information is sent to the central management device 30 via the communication means 40.

The communication means 40 uses a public telephone line 41, etc., and has communication modems 42, 43 on the terminal device 20 side and central processing device 30 side, wherein the communication modem 43 on the central processing device 30 side is connected to a line control device 44.

The central management device 30 comprises a computer 31, a keyboard 32, a CRT display device 33, a memory 34, and an automatic power-up device 35. The memory 34 is used to store the medical data, treatment indicators and condition indicators of each patient and stores such medical data as medical history, treatment history, test data, symptoms and basic data. As treatment indictors, the upper limit and lower limit of blood sugar level that are acceptable for each patient are stored for conditions with food and without food in the patient's stomach, in order to determine abnormality in blood sugar level. In addition, the maximum amount of insulin to be used, as well as the amount of change per each treatment change (that is, the unit of increase or decrease to be instructed when the program determines that the amount of insulin should be increased or decreased), are stored as limitations on the treatment method that can be instructed to the patient by this system.

Also stored as the condition indicators include generation and continuation of low blood sugar level and high blood sugar level of the patient, and such information is utilized to perform diagnosis, and also to determine the treatment method and make judgment on the need for direct examination at the medical institution that are explained later. Also, the computer 31 has a first program that performs diagnosis, determines the treatment method, makes judgment on the need for outpatient visit, generates data and performs other processes every time the patient starts the terminal device 20 as shown in Fig. 2, and this computer 31 also has a second program that displays the patient data and treatment indicators and makes changes according to the request of the doctor. Through these programs, the computer 31 can execute the processes explained below.

[2] Processing functions of the first program

[2].1 Diagnosis

The processing functions pertaining to the present invention are not such that an initial diagnosis is performed without examination by the doctor. Accordingly, a diagnosis is performed to determine if the clinical condition of the patient to be managed has changed from the previous condition as understood by the attending doctor prior to the use of the system proposed by the present invention. For this reason, questions regarding the symptoms, factors that promote the disease, implementation condition of the treatment instructed beforehand by the doctor to the patient, and blood sugar measurement request, are sent to the terminal device 20 via the communication means 40, and then reply information is received, in order to perform diagnosis on the diabetes and its potential complications based on the reply information as well as the medical data and treatment indicators stored beforehand in the memory 34.

As for the aforementioned symptoms, first applicable symptoms are selected from 16 options including dryness in the mouth, loss of appetite, bloating, disturbance of consciousness, drop in vision, pain, etc., after which detailed items specified under each of the aforementioned items are selected and questions are asked as to the degree of each symptom and whether or not associated symptoms are present. The patient can input data according to a menu format, whereby the patient selects his or her own condition from among the items displayed on the display device 23 and inputs the applicable number.

Also, questions are asked regarding factors that promote the disease and implementation condition of the treatment, if the measured result of blood sugar level deviates from the limits stored in the memory 34, in order to investigate the cause of such deviation.

[2].2 Determination of treatment method and judgment on the need for direct examination at the medical institution

In general, transitional data of blood sugar level, etc., is not sufficient as the basis on which to determine the treatment method for diabetes. On the other hand, the system proposed by the present invention is structured in such a way that the treatment method can be determined based on continuous recording of blood sugar level, etc. Accordingly, this system is equipped with multiple procedures to determine the treatment method and make judgment on the need for direct examination at the medial institution, and the procedure to be actually utilized is selected according to the aforementioned condition indicators.

For example, let's assume that for the first time the patient's measured blood sugar level has reached a high level that exceeds the upper limit set as one of the aforementioned treatment indicators. In this condition, the cause of the blood sugar increase is investigated, as mentioned above. If the applicable cause is identified as a result of this investigation and the cause is something that does not require the doctor's judgment for improvement, such as neglect of the instructed treatment, then immediately an improvement action is instructed. If the cause is something that requires the doctor's examination such as fever, the patient is instructed to receive examination at the medical institution. If the cause cannot be identified, history data (H1) is recorded under the applicable condition indicator to indicate generation of high blood sugar level.

The next time the patient utilizes this system, a processing procedure corresponding to the aforementioned history data of high blood sugar level is started. If the blood sugar level remains high, history data (H2) is recorded under the applicable condition indicator to indicate this condition. If the blood sugar level has dropped to a normal range, the history data is cleared.

This way, a need for change in the treatment method is determined if a high blood sugar level has occurred continuously for the specified number of times or more, or frequently, despite the fact that the treatment details that have been instructed are adhered to, in which case the system first asks questions to the patient regarding whether or not the diet therapy or exercise therapy can be changed (whether the intake calories can be decreased or amount of exercise can be increased). If either option is possible, the applicable change is instructed. If neither option is possible, a drug therapy is examined and a new amount of insulin is instructed that corresponds to the sum of the current amount of insulin and the amount of increase stored as the applicable treatment indicator, provided that the sum does not exceed the maximum amount of insulin stored as the applicable treatment indicator. If it is also impossible to increase the amount of insulin due to limitations by the maximum amount of insulin, the system determines that the treatment method must be reexamined by the attending doctor and instructs the patient to receive examination at the medical institution.

Examples of treatment indicators used by this system are shown below.

[2].2.1 Insulin therapy

Administered amount (injected amount)

[Units per day]

Current amount	Allowable maximum amount	Amount of each change
Patient taking lower dose: 6 to 8	Current amount + 4	1
Patient taking higher dose: 30 to 40	Current amount + 10	2

Needless to say, the allowable maximum amounts shown above are averages and the specific amount varies with each patient according to his or her clinical condition and attitude for treatment.

* Definition of amount of insulin

The amount of insulin is defined not by weight or volume, but by bioactivity (immune response), and is expressed in units.

[2].2.2 Diet therapy

As the intake calories, normally "Standard weight (calculated from the height) x 30 Cal" (1800 Cal/day if the patient weighs 60 kg) is instructed for a day.

As a unit of decrease when the high blood sugar level continues, a decrease by 80 Cal or 160 Cal (80 Cal constitutes one unit) is instructed.

[2].3 Addition and update of the patient's medical data

The symptoms, blood sugar level and other information input by the patient, as well as changes to the treatment method, instructions for receiving examination at the medical institution and condition indicators and other information generated by the program, are added or updated and stored in the memory 34 as the patient's medical data.

[2].4 Function to prohibit system use

If the patient's ID is one for which use of the system is prohibited by the doctor, a second program to be explained later stops the system with respect to all of the aforementioned functions and displays on the display device 23 only the reason for prohibition of system use that has been input via the second program.

[3] Processing functions of the second program

The second program is started by a startup command from the keyboard 32 and can display on the CRT display 33 the patient's medical data and treatment instructions input beforehand in the memory 34 or recorded by the operation of the first program, for each item selected by the input means 32, while also allowing via the keyboard 32 for addition, change and recording of the doctor's diagnosis results, test data, etc., obtained through direct examination conducted at the medical institution or change of treatment instructions.

So that use of the first program can be prohibited for patients for whom continuous use of this system has been deemed inappropriate based on the patient data displayed, the ID of each applicable patient and reason for prohibition can be stored in the memory 34 using the keyboard 32.

[4] System implementation procedure

The implementation procedure of the system used in this example is explained below based on Fig. 3.

The patient receiving home treatment turns on the terminal device 20 on the blood sugar testing date instructed beforehand by the doctor, at any time the patient desires to test his or her blood sugar level, or whenever his or her clinical condition changes. The computer 21 constituting the terminal device 20 drives the communication modem 42 of the communication means 40 connected to the computer 21, and accesses via the communication line 41 the line control device 44 and modem 43 connected to the computer 31 constituting the central processing device 30, and also accesses the automatic power-up device 35, thereby causing the automatic power-up device 35 to turn on the computer 31. When the power is turned on, the computer 31 first requests the patient to input the ID in order to verify the accessing patient. Upon receiving the ID from the patient, the computer 31 reads from the memory 34 the medical data and treatment indicators of the patient corresponding to the applicable ID, if use of this system is permitted for the ID, and the first program is started. If use of the system is prohibited for the received ID, the reason for prohibition that has been input by the doctor is displayed on the display device 23, and if the received ID is one that is not yet registered, operation of the system is stopped immediately.

When the first program is started, questions regarding the symptoms, implementation condition of the treatment method, etc., are asked according to the aforementioned format and blood sugar test is instructed, and then diagnosis is performed, the treatment method is determined and judgment is made on the need for direct examination at the medical institution based on the results of the questions/test as well as the patient's medical data and treatment indicators, after which an explanation of the result and reason is displayed to the patient and the data reported by the patient, blood sugar level, and changes to the diagnosis/treatment method and instruction for receiving examination at the medical institution made or given by this system are added or updated and recorded as the patient's medical data in the memory 34, after which the computer 31 is turned off.

On the other hand, the attending doctor can turn on the computer 31 when seeing the applicable patient via an outpatient visit or at any time the doctor desires, and start the second program from the keyboard 32. When the second program is started, the computer 31 first asks the ID of the applicable patient and then displays the medical data, treatment indicators and other items to be displayed. The doctor can select the applicable items to display on the CRT display device 33 the data

of desired items or trend graph of blood sugar level, and also store the result of diagnosis performed by the doctor or results of additional tests performed at the medical institution, or change the treatment indicators or prohibit a specific patient from using the system.

Fig. 4 shows a display example of treatment progress as mentioned above.

As explained above, the home treatment system illustrated in this example allows the patient to receive an evaluation of his or her blood sugar level or symptoms or guidance on the treatment method at home and at any time the patient desires, which saves the time to visit the hospital while ensuring appropriate treatment.

Furthermore, the patient can know whether or not visiting the hospital is necessary under certain situations such as when a change in symptom is felt, which removes any unnecessary anxiety regarding the disease and allows the patient to lead a normal social life. Also, the patient can receive blood sugar data and its evaluation, etc., in details in daily life and thus can understand the relationship between the treatment method and change in his or her clinical condition, which raises the patient's awareness of the importance of managing the disease by oneself. On the other hand, the doctor can provide advice and guidance for the patient automatically within the limitations set for the patient by the doctor himself/herself, which saves labor. Also, data of the patient's condition in his or her daily social life is automatically generated to allow for patient management that cannot be achieved in an inpatient treatment environment.

As explained above, this system can improve the quality of treatment compared to the conventional patient management solely dependent on outpatient visit, while reducing the burden on the part of the patient as well as the doctor and ensuring a speedy discharge of hospitalized patients.

Although this example describes a system for diabetic patients, the present invention is not at all limited to this example and it can also be used for other chronic diseases such as hypertension, cardiac diseases, renal diseases and hepatic diseases. If the present invention is applied to hypertension, a blood pressure meter or electrocardiograph can be used favorably as the living body information measuring device. If it is applied to hepatic diseases, a device to measure blood GOT and GPT can be used favorably as the living body information measuring device. Also, while this example uses a keyboard as the data input device and a liquid crystal display or CRT as the display device, the present invention is not at all limited to the foregoing and it is also possible, for example, to use an input device or display device operated by voice.

[Effects of the Invention]

As explained above, the present invention allows the patient to communicate with the attending doctor from home regarding data on the progress of treatment, and the instructed treatment method can also be changed by the computer within the specified limits based on treatment indicators. Because direct diagnosis by the attending doctor is not required and treatment can be continued within the specified range, the patient undergoing long-term treatment can substantially reduce the burden associated with treatment in terms of time.

Also, the aforementioned changes to the treatment method according to diagnosis by the computer are made within the limits set by predefined treatment indicators, so dangers associated with computer diagnosis can be avoided without fail.

4. Brief Description of the Drawings

Fig. 1 is a schematic structural diagram showing a favorable example of a home treatment assisting system conforming to the present invention, where the diagram illustrates a condition where a central management system is connected to a single terminal device.

Fig. 2 is an explanation drawing showing the processing procedures of a first program and a second program used by the central processing device in this example.

Fig. 3 is a flowchart showing the implementation procedure of the system in this example.

Fig. 4 is an explanation drawing showing an example of individual patient data in this example.

10 --- Living body information measuring device
20 --- Terminal device
30 --- Central processing device
40 --- Communication means

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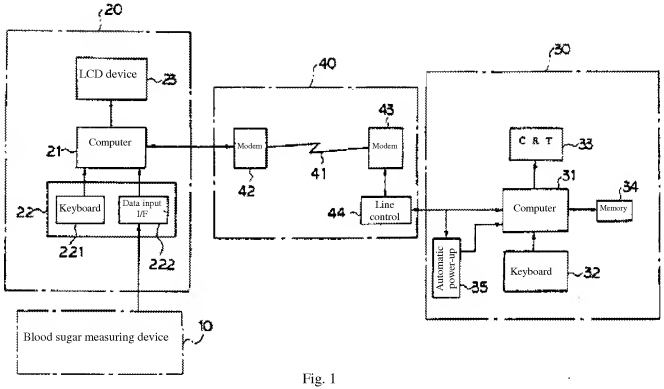
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Keyboard
Data input I/F
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Modem
42
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Modem
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Line control
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C R T
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34
Computer
Memory
Keyboard
32
Automatic power-up
35

Fig. 1

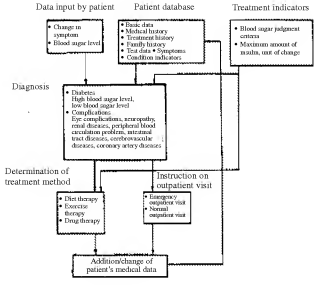

Fig. 2

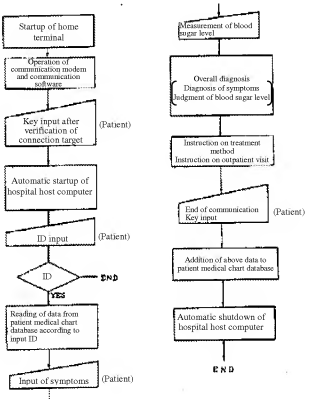

Fig. 3

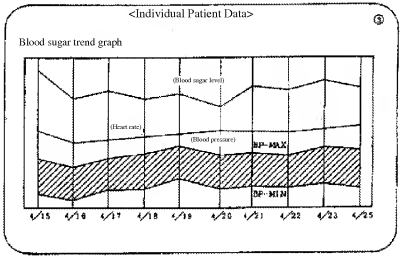

Fig. 4

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